

MINISTRY OF ECOLOGY, SUSTAINABLE DEVELOPMENT, TRANSPORT AND HOUSING

Decree no. 2012-232 of 17 February 2012 on the annual declaration on substances at nanoscale in application of article R. 523-4 of the Environment code

NOR: DEVP1123456D

Public concerned: companies producing, distributing and importing substances at nanoscale, private and public research laboratories.

Object: procedure for the declaration of the production, distribution or import of substances at nanoscale to the administration.

Entry into force: 1st January 2013, with the exception of the provisions on sanctions, which will enter into force on 1st July 2013.

Notice: articles L. 523-1 to L. 523-3 of the Environment code provide for the obligation to declare the quantities and uses of substances at nanoscale produced, distributed or imported in France. This procedure is intended to improve the knowledge of these substances and their uses, to ensure the traceability of sectors using these substances, to improve the knowledge of the market and the volumes sold, and to obtain available information on their toxicological and ecotoxicological characteristics.

The decree specifies that the declaration must be submitted to the Ministry of environment, for this purpose, before the 1st May each year. A declaration is mandatory if the minimum quantity of 100 grams of substance has been produced, imported or distributed during the previous year.

The declarations, and the data contained therein, are managed by the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES - French agency for food safety, the environment and labour).

The decree also provides for the possibility of requesting that the information declared remains confidential, if the disclosure of this information could breach industrial or commercial secrecy clauses.

References: the decree enforces article 185 of law no. 2010-788 of 12 July 2010 on the national commitment to the environment; the text amended by this decree may be consulted, as the version after this modification, at the Légifrance site (<http://www.legifrance.gouv.fr>).

The Prime Minister,

On the report by the Minister of Ecology, sustainable Development, Transport and Housing,

Having regard to EC regulation no. 1907/2006 of the European Parliament and the Council of 18 December 2006 on the Registration, Evaluation, Authorisation and restriction of CHEMicals (REACH), creating a European chemicals agency, amending directive 1999/45/EC and repealing EEC regulation no. 793/93 of the Council and EC regulation no. 1488/94 of the Commission and directive 76/769/EEC of the Council and directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission, particularly article 3 thereof;

Having regard to the Environment code, in particular its articles L. 523-1 to L. 523-5;

Having regard to the Public health code, in particular its articles L. 5141-1, L. 5141-2, R. 5161-1 and R. 5311-1;

Having regard to law no. 2000-321 of 12 April 2000 amended on the rights of citizens in their relations with administrations, particularly article 21 thereof;

Having heard the Conseil d'Etat (=French highest jurisdiction), public works' section,

Decreases the following:

Article 1

The title II of volume V of the regulatory section of the Environment code is entitled as follows: "Chemicals, biocides and substances at nanoscale".

Article 2

The following section IV is added subsequent to chapter III of title II of volume V of the Environment code:

""SECTION IV

""*Prevention of risks for the health and the environment caused by exposure to substances at nanoscale*

"**Art. R. 523-12.** – For the purposes of this section:

"**Substance at nanoscale**": substance as defined in article 3 of EC regulation no. 1907/2006, intentionally produced at nanometric scale, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for a minimum proportion of particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.

"In specific cases and where warranted by concerns for the environment, health, safety or competitiveness, this minimum proportion may be reduced. This minimum proportion is specified in a joint order issued by the Ministers of environment, agriculture, health, labour and industry. By derogation from this definition, fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as substances at nanoscale.

"For the purposes of this definition, the terms "particle", "agglomerate" and "aggregate" are defined as follows:

"a) "Particle" means a minute piece of matter with defined physical boundaries,

"b) "Aggregate" means a particle comprising of strongly bound or fused particles,

"c) "Agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.

"**Substance at nanoscale contained in a mixture without being linked to it**": substance at nanoscale intentionally introduced in a mixture from which it is likely to be extracted or released under normal or reasonably foreseeable conditions of use.

"**Territory**": French territory, excluding New Caledonia, French Polynesia, Wallis and Futuna, and French Southern and Antarctic land.

"**Manufacturer**": any party, in the course of its professional activities in the territory, that manufactures a substance at nanoscale, on its own or contained in a mixture without being linked to it, or a material intended to reject such a substance under normal or reasonably foreseeable conditions of use, for its own use or in view of their transfer free of charge or for consideration.

"**Importer**": any party, in the course of its professional activities, introducing into the territory from another Member state of the European Union or a Third party state a substance at nanoscale, on its own or contained in a mixture without being linked to it, or a material intended to reject such a substance under normal or reasonably foreseeable conditions of use.

"**Distributor**": any party established in the territory, including retailers, providing storage and transfer services, free of charge or for consideration, intended for professional users, for a substance at nanoscale, on its own or contained in a mixture without being linked to it, or a material intended to reject such a substance under normal or reasonably foreseeable conditions of use.

"**Professional user**": any party established in the territory, other than the manufacturer or the importer, which uses a substance at nanoscale, on its own or contained in a mixture without being linked to it, or a material intended to reject such a substance under normal or reasonably foreseeable conditions of use, in the course of its professional activities.

"**Scientific research and development**": any scientific experimentation, analysis or research, as defined in article 3 of EC regulation no. 1907/2006.

"**Product- and process-orientated research and development**": any scientific development related to product development or the further development of a substance, as defined in article 3 of EC regulation no. 1907/2006.

"**Art. R. 523-13.** – Each manufacturer, importer and distributor of a substance at nanoscale, on its own or contained in a mixture without being linked to it, or in material intended to reject such a substance under normal or reasonably foreseeable conditions of use, shall submit the declaration required according to article L. 523-1

if they produce, import or distribute at least 100 grams of this substance annually.

"This declaration shall be addressed to the Minister of the environment each year before 1 May. It shall refer to the previous calendar year and contain the data required according to article L. 523-1. The declarations, and the data contained therein, are managed by the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (*French agency for food safety, the environment and labour*).

"A joint order issued by the Ministers of environment, agriculture, health, labour and industry specifies the content and conditions for the presentation of this declaration.

"Art. R. 523-14. – If a substance at nanoscale, on its own or contained in a mixture without being linked to it, or a material intended to reject such a substance under normal or reasonably foreseeable conditions of use, is produced, imported or distributed in the context of scientific research and development activities without placing on the market, the declaring party may simply declare its identity and the related business segment.

"Art. R. 523-15. - If the manufacturers, importers and distributors referred to in article R. 523-13 are public research bodies, the declarations submitted by these bodies may be a unique declaration covering all of their research activities.

"A joint order issued by the Ministers of environment and research specifies the content and conditions for the presentation of this unique declaration.

"Art. R. 523-16. - If the declaration referred to in articles R. 523-13 to R. 523-15 is incomplete, the French agency for food safety, the environment and labour shall ask the declaring party to complete the declaration or to provide the additional information required within two months.

"Art. R. 523-17. - The information required according to article R. 523-2 shall be transmitted/sent to the French agency for food safety, the environment and labour within a period of two months from the receipt of the letter addressed by the Minister of the environment requesting these elements.

"Art. R. 523-18. - The declaring party shall state which information it requests to be considered as confidential when disclosure to the public would breach industrial or commercial secrecy clauses or intellectual property rights for the results of research. This request shall be justified.

"Information contained in a patent application shall remain confidential up to/until the publication of the patent. The declaring party shall inform the Minister of the environment of this publication in the following declaration.

"If a substance at nanoscale, on its own or contained in a mixture without being linked to it, or a material intended to reject such a substance under normal or reasonably foreseeable conditions of use, is produced, imported or distributed in the context of product and process orientated research and development activities focusing without placing on the market, the information declared shall be systematically considered as confidential, without need for the declaring party to request this status.

"Art. R. 523-19. - The disclosure to the public provided for in articles L. 523-1 and L. 523-2 shall occur each year, six months after the deadline for the declaration at the latest.

"Art. R. 523-20. - If a party required to submit a declaration in application of article L. 523-1 of the Environment code wishes to benefit from the derogation from public disclosure provided for in the third subparagraph of this article, the party shall state this requirement in its declaration. The declaring party shall then send a request for a derogation with justification to the Minister of defence within a maximum of five days from the date of the declaration.

"The derogation is granted by the Minister of defence. The derogation shall be notified to the applicant and forwarded to the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (*French agency for food safety, the environment and labour*). Should no explicit decision be notified within three months of the receipt of the request, the latter is considered to be rejected.

"A joint order issued by the Minister of defence and the Minister of the environment shall specify the conditions for the presentation and filling out of requests for derogations.

"Art. R. 523-21. - If a manufacturer, an importer or a distributor fails to submit the declarations provided for in article L. 523-1 by the deadline provided for in article R. 523-13 or if the information requested from a declaring party in application of article R. 523-16 or the information requested from a manufacturer, an importer or a user in application of article R. 523-17 is not submitted prior to the deadlines provided for by these two articles, the Minister of the environment may order the payment of a fine equal to 3000 euros or less and a daily penalty of 300 euros from the date of the decision in question and up to compliance with the obligation."

Article 3

Articles R. 523-12 to R. 523-20 of the Environment code, in the versions drafted based on article 2 of this degree, shall enter into force on 1 January 2013. Article R. 523-21 shall enter into force on 1 July 2013.

Article 4

I. – Title V drafted as follows is added to volume 1 of the fifth part of the Public health code (regulatory section):

TITLE V

"HEALTH PRODUCTS CONSISTING, IN PART OR IN WHOLE, OF GENETICALLY MODIFIED ORGANISMS

"This title includes no regulatory provisions."

II. – A title VI drafted as follows is added:

TITLE VI

"HEALTH PRODUCTS CONTAINING SUBSTANCES AT NANOSCALE"

"Art. R. 5161-1. - Articles R. 523-12 to R. 523-21 of the Environment code apply to substances at nanoscale contained in sanitary products intended for human use, cosmetic products as mentioned in article L. 5311-1 and the veterinary drugs mentioned in articles L. 5141-1 and L. 5141-2. "

Article 5

- Article R. 253-13, drafted as follows, is added after article R. 253-13 of the Rural and maritime fishing code :

"Art. R. 253-13. - Articles R. 523-12 to R. 523-21 of the Environment code apply to substances at nanoscale contained in the products mentioned in article L. 253-1 of this code. "

Article 6

The Minister of defence and veterans, the Minister of ecology, sustainable development, transport and housing, the Minister of the economy, finances and industry, the Minister of labour, employment and health, the Minister of agriculture, food, fishing, rurality and territorial planning and the Minister of higher education and research, each in respect of its own interests, are responsible for implementing this decree. This decree shall be published in the French *Journal officiel* (JORF).

On **17 February 2012**.

By the Prime Minister: FRANÇOIS FILLON.

Signed by the Minister of ecology, sustainable development, transport and housing, NATHALIE KOSCIUSKO-MORIZET, the Minister of defence and veterans, GÉRARD LONGUET, the Minister of the economy, finances and industry, FRANÇOIS BAROIN, the Minister of labour, employment and health, XAVIER BERTRAND, the Minister of agriculture, food, fishing, rurality and territorial planning, BRUNO LE MAIRE and the Minister of higher education and research, LAURENT WAUQUIEZ.